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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3771	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/769,962	SCHAEFFER ET AL.	
	Examiner	Art Unit	
	KRISTEN C. MATTER	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the amendment filed 12/5/2007. Per the interview summary of 3/10/2008, the previous Action mailed 2/21/2008 has been vacated. Currently, claims 1 and 3-32 are pending in the instant application.

Allowable Subject Matter

The indicated allowability of claims 5, 10, 11, and 32 is withdrawn in view of the newly discovered reference(s) to Cox and Stuart. Rejections based on the newly cited reference(s) follow. Examiner sincerely apologizes for any inconvenience.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 9, and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cox (US 4,340,046).

Regarding claims 1 and 3, Cox discloses a trach tube comprising a hollow tubular body (12) having a proximal and a distal end portion and a curved portion intermediate the proximate and distal end portions (see Figure 3; both in use the tube curves and the coagulations themselves can be considered a curved portion); and a flange (16) situated at said proximal end portion and

extending radially therefrom (see Figure 1), said flange being capable of selective attachment to said tubular body and removal therefrom by a snap-fit (column 5, lines 4-11).

Regarding claim 9, Cox discloses an inflatable cuff (14) surrounding a part of the distal end portion and an inflation line (54) connecting the cuff to a source of inflation fluid.

Regarding claims 12-14, Cox discloses an insertion device comprising a trach tube (10) and a loading dilator (18), the trach tube having a longitudinal bore and a tapered distal tip (see Figure 2); the loading dilator having a larger-diameter stepped proximal portion (near reference character 70 in Figure 2) and a smaller diameter distal portion (68) extending from said larger diameter proximal portion, said smaller diameter portion having a generally cylindrical profile and a tapered distal end (72), the smaller diameter portion being sized to be insertable through the longitudinal bore of said trach tube such that the tapered distal end extends axially beyond the tapered distal tip of the trach tube (see Figure 3), the trach tube further comprising a stop portion/larger-diameter collar (64) at said proximal end for engaging a distal portion of the larger-diameter stepped portion of the dilator to limit axially movement of the dilator through the trach tube (see Figure 3). Note that the term "portion" has no definite structural limitation and can include sections of varying diameter and as interpreted by examiner the smaller diameter portion includes tip 72 and tube 68, both of which have a smaller diameter than the smallest diameter of the stepped portion 70.

Regarding claims 15 and 16, as seen in Figure 3, the tapered end of the trach tube and the dilator are complementary such that a generally smooth conical insertion tip is defined thereby and has a profile sufficient for dilating an opening in the body of a patient for inserting of said trach tube.

Regarding claim 17, the stepped proximal portion of the dilator comprises a gripping surface (i.e., user grasps the end of the portion 70 to remove the dilator).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox.

Regarding claims 18-20, Cox is silent as to the material of the insertion device or the device being molded integrally. However, absent a critical teaching and/or a showing of unexpected results from making the gripping surface from one of the claimed polymers or integrally molding the dilator components, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the dilator from a thermoplastic polymer and/or to have integrally molded the dilator components because such materials and processes are well known and commonly used in the art for easily making trach tubes and their associated components comfortable, durable, and biocompatible. Furthermore, it appears as though the device of Cox would perform equally well if made of a thermoplastic polymer or integrally molded.

Regarding claim 21, Cox does not specifically disclose that the stepped portion includes a longitudinal passageway that receives a portion of the smaller diameter portion. However, absent a critical teaching and/or a showing of unexpected results from securing the smaller diameter portion in a longitudinal bore of the stepped portion, examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have secured the

smaller diameter portion in a longitudinal bore of the stepped portion because it would have provided a well known and commonly used means for permanently securing the pieces together (i.e., either interference fit or with an adhesive in the bore for example) in such a way that the pieces would not become separated during removal of the dilator.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1, 3, 9, and 12-17 above, and further in view of Stuart (US 5,778,877). Cox is silent as to a collar with a groove for mating with a cut-away portion (38) of the flange or snap-fitting with a receptacle on the tubular body. However, Stuart discloses, in a similar trach tube device, a collar (12) with a groove (34, 36) for cooperatively engaging a flange cut-away portion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the tube of Cox with a collar including a groove as taught by Stuart and to have moved a snap-fit component (either a snap or a barb) onto the collar in order to allow the flange to pivot as needed on the patient's neck as taught by Stuart. Whether the collar is integral with the hollow tubular body or not is considered an obvious design consideration to one of ordinary skill in the art because both integral and removable collars are well known and commonly used in the art. Furthermore, it appears as though the device of Cox would perform equally well with the snap fit components on each flange half being connected to a collar as opposed to just the other half of the flange (see figures 4-6 of Cox).

Claims 8 and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1, 3, 9, and 12-17 above, and further in view of Varner (US 6,105,577).

Regarding claim 8, Cox is silent as to inserting a removable inner cannula into the tubular body. However, Varner discloses, in a similar trach tube, a removable inner cannula (128). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cox's device with a removable inner cannula as taught by Varner to use as a liner that can be removed and cleaned for the more permanent trach tube.

Regarding claim 22, Cox discloses a device for percutaneous insertion into the trachea comprising a trach tube having a longitudinal passageway there through, said trach tube having a proximal end exterior to the trachea and a distal end portion insertable into the trachea, said trach tube further having and a flange (16) situated at said proximal end portion and extending radially therefrom (see Figure 1), said flange being capable of selective attachment to said tubular body and removal therefrom by a snap-fit after the distal end portion has been inserted into the trachea (column 5, lines 4-11); and a dilator (18) for inserting into the longitudinal passageway for dilating an opening in said trachea.

Cox is silent as to a locking assembly for locking the trach tube to the dilator during insertion of said trach tube. However, Varner discloses an inner cannula including locking means (130) for securing the tube to the trach tube. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have including the locking means taught by Varner in the dilator of Cox in order to secure the dilator to the trach tube during insertion so that the tapered distal tip didn't accidentally slip axially up into the trach tube. Furthermore, it appears as though the device of Cox would perform equally well with a locking means as taught by Varner because the locking means allows removal of the cannula/dilator as needed.

Regarding claim 23, the locking assembly of Varner includes a securement member (130) engageable with a complementary member (117) on the trach tube.

Regarding claim 24, the collar/cap bottom surface of the locking assembly is considered a stop member disposed on an outer surface of the dilator to prevent excess axial movement of the dilator into the trach tube (as is also disclosed by Cox and collar 64 stopping movement via handle 70). The stop member is engageable with the securement member and complementary member of the locking assembly and is prevented from sliding along the dilator when axial force is applied by virtue of the tight fit (especially if only a small amount of axial force is applied). Varner does not specifically disclose that the collar is permanently attached or that it slides along the tube, but it would have been obvious to have permanently secured the stop member/collar to the tube such that the components fit together without having excess tube extending beyond the collar (i.e., to prevent movement with even larger axial forces).

Regarding claims 25-26, the collar of Varner is a fitted annular ring. As discussed above, even though Varner is silent as to the collar being permanently secured to the tube, examiner contends that is would have been obvious to one of ordinary skill in the art to permanently attach the collar to the tube (i.e., via adhesive for example), thus making the stop member integral with the dilator.

Regarding claims 27 and 28, the complementary member of Varner includes a collar on the trach tube (see Figure 4). Whether the collar is integral with or fitted on the tube is considered an obvious design consideration to one of ordinary skill in the art because integral collars and fitted exterior collars are both well known and commonly used in the art for permanently securing collars to trach tubes. Furthermore, it appears as though the locking

assembly of Varner as used in Cox would perform equally well if the collar were either integral or fitted exteriorly.

Regarding claim 29, Varner discloses slot securement members not screw threads. However, absent a critical teaching and/or showing of unexpected results from using threads examiner contends that teeth/slots and threads are well known equivalents for removably securing two pieces together and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced the teeth/slots with threads because threads would have provided a well known and commonly used means for removably securing the two tubes together. Furthermore, it appears as though the locking assembly of Varner would have performed equally well with threads as opposed to teeth/slots.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1, 3, 9, and 12-17 above, and further in view of Collins (US 6,799,574). Cox discloses the inflation line as threaded through loops but is silent as to the line being peelable. However, Collins discloses a peelable inflation line that allows the inflation line to be kept neatly with the tube shaft along most of the length (column 3, lines 55-60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Cox to include a peelable inflation line as taught by Collins in order to keep the inflation line neatly with the tube shaft. Furthermore, it appears as though the device of Cox would perform equally well with a peelable inflation line.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox as applied to claims 1, 3, 9, and 12-17 above, and further in view of Lester (US 5,928,198). Cox is silent as to a central lumen extending substantially through the loading dilator. However, Lester discloses a loading dilator (2) having a central lumen (25) extending substantially there through. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Cox's dilator with a central lumen as taught by Lester in order to allow the patient to breath while the device is being inserted.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Rutter (US 7,140,369). The method steps claimed would have directly resulted from use of the Cox device as described above with respect to claim 1. The only difference between the instant claim and Cox is the step of trimming an excess portion of the proximal end portion of the tubular body. However, Rutter discloses that trimming the proximal end of a trach tube is well known in the art for accommodating various sizes of patients such as pediatrics and adults (column 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have trimmed the tube of Cox for accommodating patients of varying sizes as taught by Rutter.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Collins as applied to claim 10 above, and further in view of Rutter. Cox as modified by Collins is silent as to trimming the tubular body to a trim line and the inflation line being peelable to a point below the trim line. However, Rutter discloses that trimming the proximal end of a trach tube is

well known in the art for accommodating various sizes of patients such as pediatrics and adults (column 4, lines 5-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have trimmed the tube of Cox as modified by Collins to a location above where the inflation line can be peeled for accommodating patients of varying sizes as taught by Rutter.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cox and Rutter as applied to claim 30 above, and further in view of Stuart. The modified Cox device is silent as to the flange being attached to a collar. However, Stuart discloses, in a similar trach tube device, a collar (12) for cooperatively engaging a flange. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the tube of Cox with a collar as taught by Stuart in order to allow the flange to pivot as needed on the patient's neck or for added support. Furthermore, it appears as though the device of Cox would perform equally well with a collar for engaging the flange.

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Crandall et al. is cited to show another removable flange on a trach tube, LaBombard

is cited to show another flange that engages a collar on a trach tube, Shelden et al. is cited to show another tapered trach tube and loading dilator with a flange, Shiley et al. is cited to show another pivoting flange and tapered loading dilator, and Ranford et al. is cited to show another removable flange on a trach tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN C. MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771